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| MICHAEL W. HAAS RESPIRONICS, INC. 1010 MURRY RIDGE LANE MURRYSVILLE, PA 15668 | | | EXAMINER THOMAS, JONATHAN B | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/623,328
Filing Date: July 18, 2003
Appellant(s): LATTNER ET AL.

Richard J. Coldren
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 3/18/2008 appealing from the Office action mailed 9/28/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

| | | |
|------------------|-----------------|----------------|
| 5,190,053 | Meer | 3-1993 |
| 5,365,945 | Halstrom | 11-1994 |
| 4,414,982 | Durkan | 11-1983 |

***In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)**

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Note that the below cited rejection is written in terms of Halstrom in view of Meer not Meer in view of Halstrom as previously done in the non-final rejection dated 6/15/2007 and the final rejection dated 9/28/2007. This change has been made to increase the clarity of the rejection and was not necessitated by amendment or argument by the applicant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 43-47 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halstrom 5,365,945 in view of Meer 5,190,053.

Halstrom teaches mandibular positing means 20 and members adapted to engage a structure associated with a patient's upper dentition and mandible and means for limiting the movement of one relative to the other 28, 32, and 40 respectively however Halstrom does not teach the following claimed limitations taught by Meer: electromuscular stimulating means 10, electrode positioning means 24, respiration detecting means and means for controlling a delivery of electrical energy (Col. 2 ll. 56-66).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the Halstrom apparatus in view of Meer in order to provide supplemental apnea therapy. Note that Meer discloses that neither mandibular positioners nor geniglossus muscle stimulators are completely effective at treating obstructive sleep apnea (Col 1 ll. 56-59).

Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Halstrom in view of Meer as applied to claims 43-47, and 49 above, and further in view of Durkan 4,414,982.

Halstrom and Meer teach the apparatus described above, however they do not teach the following limitation taught by Durkan: Means for providing a positive pressure to an airway 22. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the Meer and Halstrom apparatus as described above with the airway of Durkan to supply oxygen to a patient substantially throughout the duration of an inspiration (Col. 1 ll. 36-39).

Method claims 50-54, and 56 are rejected because the apparatus of Halstrom in view of Meer as applied to claims 43-47, and 49 above performs the method steps as claimed.

Method claim 55 is rejected because the apparatus of Halstrom in view of Meer in view of Durkan as applied to claim 48 above performs the method steps as claimed.

Claims 57,58, and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meer in view of *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Meer teaches the first and second electrodes 12, first and second support members 24, respiratory sensor (Col. 2 ll. 56-66), stimulation through at least a portion of inspiration (Col. 6 ll. 44-47), and support member coupling 18 and 20, but it does not teach the following claimed limitations: posterior to anterior or anterior to posterior electrode placement and stimulation nor stimulation start time prior to onset of inspiration.

However is has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) MPEP 2144.05 II A.

(10) Response to Argument

A. Rejection Under 35 U.S.C. 103(a) over U.S. Patent Number 5,190,053 to Meer in view of U.S. Patent Number 5,365,945 to Halstrom.

Regarding the appellant's arguments regarding the rejection of claims 43-47, 49-54 and 56, the appellant argues that a person having ordinary skill in the art at the time

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of the invention would not have been inclined to combine Halstrom and Meer to arrive at the disclosed invention because Meer teaches away from use with tongue and jaw positioners.

It is submitted that a person having ordinary skill in the art (PHOSITA) would have been particularly drawn to combine a jaw positioning device with an electrical stimulation device in order to provide supplemental therapy. Note that Meer teaches that neither technique is completely effective (Meer Col 1 ll. 56-59).

It is further submitted that a PHOSITA would have been drawn particularly to the Halstrom device to combine with an electrical stimulation device as the Halstrom device aims to overcome the discomfort associated with prior jaw positioning devices by allowing lateral motion (Halstrom Col 2 ll. 33-39).

It is noted that the standard for an obviousness rejection is not whether a PHOSITA would have been inclined to combine the devices but instead that "A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. 103 (a) (emphasis added)

Regarding the appellant's arguments regarding the direction of stimulation, particularly the rejection of claims 44 and 51, the appellant argues that the Meer does not teach locating a second electrode posterior to the first electrode and as such the

Meer device cannot apply electrical stimulation in a posterior to anterior or anterior to posterior direction.

It is submitted that the appellant has provided how one is to determine which direction is posterior or anterior. As such the Meer electrodes, which are laterally arranged can be reasonably considered to be posteriorly and anteriorly arranged.

It is further submitted that classical human medical anatomical terminology defines anterior as being towards the head or rostral and posterior being away from the head or caudal. Note that the appellant's electrodes 146 are arranged along 150 in what is classically considered to be a dorsal-ventral manner. The Meer electrodes 12 along 24 are arranged in a similar dorsal-ventral manner Figs 9 and 2.

It is further submitted that given the specified dorsal-ventral definition of posterior and anterior and given that Meer teaches stimulation between one of its electrodes on one support structure 24 to at least one electrode on the opposite support structure (Meer Col 2 ll. 50-55), Meer discloses posterior to anterior stimulation as current flowing from one electrode 12 to more than one electrode on the opposing support structure must have a dorsal-ventral component if the are spaced apart dorsal-ventrally along the opposing support structure (Meer Figs 2 and 9).

It is noted that current flowing between Meer electrodes 12 on the same support structure 24 or different support structure passes through the volume conductor of the geniglossus muscle and as such will have at least a small component in the posterior to anterior direction regardless of how posterior and anterior are defined.

Regarding the appellant's arguments regarding electrode placement with respect to the oral cavity, particularly the rejection of claims 45 and 52, the appellant argues that Meer does not teach first and second electrodes being placed on the same side of the oral cavity.

It is submitted that Meer teaches an electrode support structure 24 which contains electrodes 12 which are all located on the same side of the oral cavity.

It is further submitted that Meer teaches that Meer's electrodes 12 in opposite support structures 24 are also on the same side of the oral cavity, that side being the caudal side of the oral cavity.

Regarding the appellant's arguments regarding electrode placement with respect to the frenulum, particularly the rejection of claims 46 and 53, the appellant argues that Meer does not teach locating a first and second electrode posterior to the frenulum and that a PHOSITA would not have located the electrodes in such a position.

It is noted that use of posterior in this claim is inconsistent with as used above. As the frenulum runs along the length of the tongue to its base, in order for an electrode to be placed posterior, as defined above, or dorsal to the frenulum, the electrode would have to be outside the oral cavity, or above the tongue. Both positioning above the tongue and outside the oral cavity are not disclosed by the applicant's specification. As such posterior in this claim is interpreted in the classical manner, meaning away from the head or rostral.

It is submitted that Meer's electrodes 12 are positioned sublingually and as such are posterior or rostral to the frenulum.

It is noted that the standard for an obviousness rejection is not whether a PHOSITA would have chosen to implement the device in the claimed manner but instead that "A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. 103 (a)

B. Rejection Under 35 U.S.C. 103(a) over U.S. Patent Number 5,190,053 to Meer in view of U.S. Patent Number 5,365,945 to Halstrom in further view of U.S. Patent Number 4,414,982 to Durkan.

Regarding the appellant's arguments regarding the rejection of claims 48 and 55, the appellant argues that a PHOSITA would not have been motivated to combine the Durkan device with the Meer device. However it is notoriously well known that positive air pressure devices are used to treat sleep apnea and a PHOSITA would have found it obvious to supplement the therapy of Meer with the therapy of Durkan in order to provide increased treatment.

C. Rejection Under 35 U.S.C. 103(a) over U.S. Patent Number 5,190,053 to Meer in view of Aller?

Regarding the appellant's arguments regarding the rejection of claims 57, 58 and 60, the appellant's assertion that the general conditions of the invention recited in claims 57, 58 and 60 are not disclosed in Meer is not persuasive. Regarding the appellant's argument that the claimed electrode positioning would not have been discovered through routine experimentation, see the above section A which shows that depending on interpretation of the term posterior, the claimed orientation of the electrodes is either taught by Meer or very close to being so and it is readily apparent that a PHOSITA would discover the claimed orientation as a matter of routine experimentation. Regarding the applicant's argument that the claimed stimulation timing would not have been discovered through routine experimentation, it is readily apparent that a PHOSITA would experiment with the timing of their device's operation as both cited active prior art devices Meer (Col 7 ll. 3-6) and Durkan (Col 3 ll. 18-21) are concerned with the timing of their therapy relative to inspiration.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

Conclusion

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section (9) above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer

exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,
Jonathan Bartholomew Thomas

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4/1/2008

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

Fred Schmidt

/Frederick R Schmidt/

Director, Technology Center

Conferees:

Carl Layno

/Carl H. Layno/

Supervisory Patent Examiner, Art Unit 3766

Angela Sykes

/Angela D Sykes/

Supervisory Patent Examiner, Art Unit 3762